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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/839,577	04/20/2001	Klaus M. Hahn	1361.007US1	1433

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EXAMINER

KAM, CHIH MIN

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 07/07/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/839,577

Applicant(s)

HAHN ET AL.

Examiner

Chih-Min Kam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-92 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-92 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U. S. C. 121:
 - I. Claims 1-5, drawn to a compound of formula (I), comprising one or more aminooxy groups, classified in class 564, subclass 300.
 - II. Claims 6-7, drawn to a peptide comprising a backbone and one or more aminooxy groups, classified in class 514, subclass 2 and class 564, subclass 300.
 - III. Claims 8-43 and 61-66, drawn to a peptide conjugate of formula (III) or (IV), comprising a peptide or an antibody as R⁶ group, and a functional molecule D; a method for preparing a peptide conjugate comprising a peptide linked to a functional molecule; and a polypeptide biosensor, classified in class 514, subclass 2, class 564, subclass 300, and 424, subclass 179.1.

Should Group III be elected, applicant is required to select a peptide or an antibody as R⁶ group; and a functional molecule (D) from claims 25-34. If biophysical probe as a functional molecule were elected, applicant is also required to elect a specific probe from claims 35 and 36, and a specific fluorescent protein from claim 66. Any peptide conjugate is considered, absent factual data to the contrary, a distinct peptide. This is not a species election.
 - IV. Claims 44-48, drawn to a method of identifying an optimal position for placement of a functional molecule on a peptide having a peptide backbone and a known activity, wherein the functional group location does not substantially interfere with the known activity of the peptide; classified in class 514, subclass 2, and class 564, subclass 300.

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V. Claims 49-60, drawn to a method of identifying an optimal position for placement of an environmentally-sensitive functional molecule on a peptide biosensor having a peptide backbone, wherein the functional group location provides the strongest signal change in response to an environmental change; classified in class 514, subclass 2, and class 564, subclass 300.

Should Group V be elected, applicant is required to select a peptide or an antibody as a peptide conjugate from claim 51. Any peptide conjugate is considered, absent factual data to the contrary, a distinct peptide. This is not a species election.

VI. Claims 67-69, drawn to a fusion protein comprising Rho GTPase protein domain linked to a fluorescent protein via a peptide conjugate, classified in class 435, subclass 69.7.

Should Group VI be elected, applicant is required to select a fluorescent protein from claim 69. Any fluorescent protein is considered, absent factual data to the contrary, a distinct protein. This is not a species election.

VII. Claims 70-72, drawn to a nucleic acid encoding a fusion protein comprising Rho GTPase protein domain linked to a fluorescent protein via a peptide conjugate; an expression vector comprising the nucleic acid; or a cell comprising the vector, classified in class 536, subclass 23.5, and class 435, subclasses 320.1 and 325.

VIII. Claims 73-75, drawn to a method of detecting GTP activation of a Rho GTPase protein in a cell using a polypeptide biosensor containing a fluorescent dye, which can undergo fluorescence resonance energy transfer with a fluorescent dye on the GTP

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activated Rho GTPase protein; classified in class 514, subclass 2, and class 564, subclass 300.

IX. Claims 76 and 78-81, drawn to a method of detecting GTP activation of a Rho GTPase protein by contacting a polypeptide biosensor with a test substance, wherein the polypeptide is operatively linked to an environmentally sensitive dye, which will emit a signal of a different lifetime, intensity or wavelength when the polypeptide biosensor is bound to the GTP activated Rho GTPase protein as to the polypeptide biosensor is not bound; classified in class 514, subclass 2, and class 564, subclass 300.

X. Claims 77 and 78-81, drawn to a method of detecting GTP activation of a Rho GTPase protein in a cell using a polypeptide biosensor, wherein the polypeptide is operatively linked to an environmentally sensitive dye, which will emit a signal of a different lifetime, intensity or wavelength when the polypeptide biosensor is bound to the GTP activated Rho GTPase protein as to the polypeptide biosensor is not bound; classified in class 514, subclass 2, and class 564, subclass 300.

XI. Claim 82, drawn to a method of detecting binding of an antibody to an antigen which comprises reacting an antibody comprising a peptide conjugate with an antigen and detecting an antibody-antigen complex; classified in class 435, subclass 7.1.

XII. Claim 83, drawn to a method of detecting binding of an antigen to an antibody which comprises reacting an antigen comprising a peptide conjugate with an antibody and detecting an antibody-antigen complex; classified in class 435, subclass 7.1.

XIII. Claims 84-90, drawn to a fluorescent compound comprising heterocyclic rings, classified in class 548, subclasses 100 and 122.

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Should Group XIII be elected, applicant is required to select a specific functional group for each R^8 , R^{11} and R^{12} from claim 82, and a specific functional group for each R^9 and R^{10} from claims 86 and 87. Any fluorescent compound is considered, absent factual data to the contrary, a distinct compound. This is not a species election.

XIV. Claims 91 and 92, drawn to a biological molecule linked to the fluorescent compound of claim 84, classified in class 548, subclass 100; class 514, subclass 2; class 424, subclass 179.1, and class 536, subclass 23.1.

Should Group XIV be elected, applicant is required to select a specific biological molecule from claim 92. Any biological molecule is considered, absent factual data to the contrary, a distinct compound. This is not a species election.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions I, II, III, VI, VII, XIII and XIV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to an aminoxy-containing compound, an aminoxy-containing peptide, an aminoxy-containing peptide conjugate, a fusion protein, a nucleic acid, a fluorescent compound, and a biological molecule containing the fluorescent compound, which are patentably distinct each from the other because they are physically and functionally distinct chemical entities and also have different utilities. For example, an aminoxy-containing compound can be used to link a peptide with a functional molecule, an aminoxy-containing peptide can be used to make peptide conjugate, a peptide conjugate can be used to make a polypeptide biosensor or a fusion protein, a nucleic acid can be used to encode

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the fusion protein, and a fluorescent compound and the peptide linked to the fluorescent compound can be used to study the binding between the proteins.

The product of Invention III and the methods of Inventions IV, V, VIII, IX, X, XI and XII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the methods of Inventions IV, V, VIII, IX, X, XI and XII are alternative processes of the use of the product of Invention III.

The products of Inventions I, II, VI, VII, XIII and XIV are distinct from the methods of Inventions III, IV, V, VIII, IX, X, XI and XII because the products of Inventions I, II, VI, VII, XIII and XIV can be neither made by nor used in the methods of III, IV, V, VIII, IX, X, XI and XII.

The methods of Inventions III, IV, V, VIII, IX, X, XI and XII are patentably distinct each from the other because they have different method steps, utilize different components and would produce different outcomes.

Because the inventions I-XIV are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and their recognized divergent subject matter, and because each invention requires different searches but are not co-extensive, examination of these distinct inventions would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

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Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

A telephone call was made to James Nelson on July 2, 2003 to request an oral election to the above restriction requirement, but did not result in an election being made.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, Ph. D. can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. *CMK*
Patent Examiner

Christopher S. F. Low
CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

July 2, 2003